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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,575	11/07/2001	William E. Mitch	133-01	6630

23713 7590 10/03/2003

GREENLEE WINNER AND SULLIVAN P C
5370 MANHATTAN CIRCLE
SUITE 201
BOULDER, CO 80303

EXAMINER

DAVIS, DEBORAH A

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 10/03/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/008,575

Applicant(s)

MITCH ET AL.

Examiner

Deborah A Davis

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 17 is/are rejected.
- 7) ☒ Claim(s) 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group III in Paper No. 7 is acknowledged. The traversal is on the ground(s) that Groups II and III should be examined together because the method steps are related. This is found persuasive and both groups will be examined together.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Applicant is invited to show support for claim 16 wherein the subject is a farm animal.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 10, has limitations in the parentheses, it is unclear whether these limitations are part of the instant claim 1, please clarify.

7. Claims 10 and 15 lack method steps such as contact, forming a complex separation and detection. It is unclear as to how the administration of a pharmaceutical is being measured against a method of preventing or reducing muscle degradation. Please clarify.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

9. Claims 10-15 are rejected under 35 U.S.C. 102(a) as being anticipated by Rudnicki et al (WO 00/491139).

Claims 10-15 is directed to a method of preventing or reducing the degradation of muscle protein in a subject having a condition that stimulates muscle protein breakdown

comprising the step of administering to the subject a caspase enzyme inhibitor.

Rudnicki et al anticipates the instant claims by teaching agents that activate and inhibit the expression of a caspase-3 activated protein kinase called the SMAK protein that is associated with apoptosis and can play a role in preventing conditions that can lead to muscle conditions such as cancerous neoplasia development, inflammation and autoimmune disease as recited in claim 12 (page 5, lines 1-24 and page 11, line 34).

Rudnicki et al also teaches a method of identifying and treating muscle atrophy (muscle degradation) (page 6, lines 8-11). Pharmaceutical agents that activate the expression of SMAK protein can be administered to modulate conditions such as cancer (page 23, lines 22-23). Under conditions where apoptotic responses are detrimental, pharmaceutical agents are also administered to inhibit the expression of the SMAK protein (page 5, lines 17-24).

These activators and inhibitors may be administered to living organisms including humans and animals as recited in claim 14. Administration of a therapeutically active amount of the pharmaceutical compositions of the present invention is defined as an amount effective at dosages and for periods of time necessary to achieve the desired result as recited in claim 10 (page 25, lines 1-8). The active substance may be administered in a convenient manner such as by injection (subcutaneous, intravenous), oral administration, inhalation, or rectal administration (page 25, lines 10-15).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rudnicki et al (WO 00/491139) in view of Wong et al (USP#6,492,124).

The teachings of Rudnicki et al are set forth above and differ from the instant claims in not teaching a PI3 Kinase inhibitor.

However, Wong et al teaches a PI3 Kinase inhibitor that block signaling in the signal transduction pathway of PKB activation in osteoclasts and dendritic cells (col. 23, lines 19-22) can provide strategies for treating osteoclast-related diseases such as osteoporosis and osteoporosis (col.1, lines 12-20).

It would have been obvious of one of ordinary skill in the art to modify the teachings of Rudnicki et al to include using a specific P13 Kinase inhibitor as taught by Wong et al to explore strategies for treating bone related disease such as osteoporosis.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- A. Kikly et al (EPO 841 399) teaches fin-1 acid (a caspase) and protein sequences and uses therefore.
- B. Weichold et al (WO 00/33654) teaches protease inhibitors to modulate cellular pathways immunity and therapies associated therewith.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (703) 308-4427. The examiner can normally be reached on 8-5 Monday thru Friday.

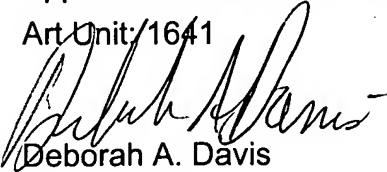
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

Application/Control Number: 10/008,575

Page 7

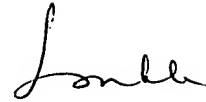
Art Unit: 1641



Deborah A. Davis

CM1, 7D16

September 25, 2003



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

09/30/03